DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 14 2009

Re: NPLATE
Docket No.: FDA-2009-E-0053

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,835,809, filed by Amgen Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for NPLATE (romiplostim), the human biological product claimed by the patent.

The total length of the regulatory review period for NPLATE is 2,319 days. Of this time, 2,014 days occurred during the testing phase and 305 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: April 19, 2002.

   The applicant claims April 23, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 19, 2002, the date of the FDA correspondence removing the clinical hold on the application.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: October 23, 2007.

   FDA has verified the applicant's claim that the biologics license application (BLA) for NPLATE (BLA 125268/0) was initially submitted on October 23, 2007.

3. The date the application was approved: August 22, 2008.

   FDA has verified the applicant's claim that BLA 125268/0 was approved on August 22, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Joseph A. Williams, Jr.
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